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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1105B

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

January 16, 1997

WARNING LETTER
CIN-WL-97-131

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Margaret & Dale Kauffman, Owners
Margandale Farms
6967 SR 754
Shreve, OH 44676

Dear Mr. & Mrs. Kauffman:

On November 4, 1996 FDA investigators conducted an inspection at your dairy farm in Shreve, Ohio. This investigation was a result of USDA tests conducted on a Jersey cow bearing back tag #31NW 1283 which you had caused to be delivered to the [redacted] and sold. The animal was slaughtered on August 28, 1996 at [redacted] in [redacted] The USDA test results showed the animal contained 5.10 parts per million (ppm) Streptomycin in the liver. There is a 0.50 ppm limit for Streptomycin in the liver of calves. The regulation lists no tolerance for this drug in cows. The USDA sample report shows the carcass and kidneys were released and the liver condemned.

This animal had been hauled to the [redacted] by [redacted] and presented for sale "as is" because it had not been withheld a sufficient period since it had been medicated. This means of disposing of medicated animals resulted in this animal being slaughtered for human food.

[redacted] Company bought the cow for $5.00 and shipped it with animals consigned for slaughter at [redacted] in [redacted] Enroute the cow was off loaded at [redacted] in [redacted] on or about August 23, 1996. Subsequently it was picked up by [redacted] and slaughtered on August 28, 1996.

The controls you exercise over animals you medicate are inadequate to prevent the introduction into interstate commerce of adulterated food in violation of Section 402(a)(2)(D) and 402(a)(4) of The Federal Food, Drug, and Cosmetic Act.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure

to promptly correct these violations may result in regulatory action without further notice, such as injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently slaughtered after shipment in interstate commerce is sufficient to hold you responsible for a violation of the Act. Your failure to notify the Auction Market of the medicated status of the cow either directly or through the services of your hauler, [redacted], resulted in this animal being bought for slaughter for human food.

The FD&C Act is a strict liability statute which requires persons in a responsible position to exercise the care necessary to prevent violations of the Act. You knew the animal was not drug residue legal, but allowed it to be sold "as is" which did not declare the animal was not drug residue legal for slaughter as human food.

You can be held responsible for the actions of employees or parties who perform work for you which result in violations of the FD&C Act. You should identify animals which are not drug residue legal to persons who haul them and assure that the animals are sold in a manner which will notify slaughter cattle buyers that the animal is not drug residue legal.

The animal is the second violative animal from your farm since the first of May 1996. You received a letter from USDA on the previous animal slaughtered May 18, 1996 at [redacted]. It was identified by back tag #304 and the liver contained 3.27 ppm Oxytetracycline which has a limit of only 0.10 ppm.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food and Drug Administration, Cincinnati District Office, Attention: Leonard J. Farr, Compliance Officer, 1141 Central Parkway, Cincinnati, Ohio, 45202.

Sincerely yours,

John R. Marzilli
District Director
Cincinnati District

LJF/clc